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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/032,659	Confirmation No. 6167
Applicant	:	Pamela A. Kramer	
Filed	:	October 25, 2001	
Art Unit	:	3773	
Examiner	:	Julian W. Woo	
Title	:	MANUFACTURE OF FINE-GRAINED MATERIAL FOR USE IN MEDICAL DEVICES	
Docket No.:	:	ACS 54306 (G2257USO1)	
Customer No.	:	24201	June 25, 2009

Mail Stop Appeal Brief – PATENTS
Commissioner for Patents

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

Dear Sir:

Applicant submits the following Response to the Notice of Non-Compliant Appeal Brief dated June 3, 2009.

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on November 7, 2008 in conjunction with a Pre-Appeal Brief and the Notice of Panel Decision from Pre-Appeal Brief dated January 23, 2009. A request for a one month extension of time along with the requisite fees is attached hereto.

INTRODUCTION

The present invention relates to medical devices such as for example stents, which often have extremely fine structures that are called upon to undergo deformation as well as bear substantial loads. More particularly, the invention is directed to the use of metals having a grain size in a specific range that had unexpectedly been found to be especially beneficial for medical device applications. The present application, U.S. Serial No. 10/032,659 was filed October 25, 2001.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Par, Illinois 60664-3500. This application was originally assigned by the inventors, PAMELA A. KRAMER and JOHN WILLIAM MORRIS, JR to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed October 11, 2001 and October 21, 2001 respectively, which was recorded by the US Patent Office on October 25, 2001 beginning at Reel 012421, Frame 0441.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The application was originally filed with 40 claims. Claims 2, 11-13, 17-21, 25 and 30-40 had been canceled. Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 are currently pending, are under final rejection and are being appealed. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final Office Action of August 13, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The rejected claims are all directed to a material for use in the manufacture of medical devices. More specifically, the claims are directed to the use of a material with a certain characteristic that had unexpectedly been found to be especially advantageous for medical device applications, and more particularly, for stents. The claims are directed to the use of metallic material having an average grain size in the range of one to ten microns.

Independent claim 1 is supported in the drawings and specification as follows:

1. A medical device (Fig. 11; page 4, lines 1-4) for use in treating a human patient, comprising:

a metal alloy substrate (page 4, line 13) having an average grain size in the range of one to ten microns (Fig. 2; page 3, lines 14-15).

Independent claim 22 is supported in the specification as follows:

22. An intravascular stent (Fig. 11, #60; page 18, line 17) for use in a body lumen, comprising:

a plurality of cylindrical rings (Fig. 11, #80; page 18, line 25) interconnected to form the stent, each cylindrical ring having a first deliver diameter and a second expanded diameter (page 18, line 5); and

each cylindrical ring being formed from a fine grained material (page 19, line 7) having an average grain size of one to ten microns (Fig. 2; page 3, lines 14-15).

Independent claims 41 is supported in the specification as follows:

41. A stent (Fig. 11, #60; page 18, line 17) comprising a substrate having an average gain size in the range of one to ten microns (Fig. 2; page 3, lines 14-15).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the Final Office Action dated August 13, 2008, claims were rejected as follows:

GROUND I

Claims 1, 9, 14-16 and 41-45 were rejected under 35 U.S.C. § 103(a) as obvious over Davidson (USPN 5,954,724).

GROUND II

Claims 22 and 26-29, were rejected under 35 U.S.C. § 103(a) as obvious over Frantzen (USPN 5,843, 175) in view of Davidson (USPN 5,954,724).

VII. ARGUMENT

Each and every claim calls for a medical device to be formed of a metallic substrate having a grain size of between one and ten microns. None of the references cited by the Examiner suggest such range of grain size. None suggest that the claimed range of grain size would reduce cracking and/or heavy slip band formation in medical devices. The issue is whether the claimed range is obvious in view of the cited art despite the complete absence of any teaching of what effect grain size would have on the performance of a medical device, let alone the complete absence of a teaching of ANY particular grain size.

GROUND I

Claims 1, 9, 14-16 and 41-45 were rejected under 35 U.S.C. § 103(a) as obvious over Davidson (USPN 5,954,724).

The Examiner asserts that the Davidson reference at col. 8, lines 21-25 (Exhibit 2) teaches a medical device having a "fine grain structure." Such assertion is inaccurate. The passage relied on by the Examiner in fact merely states:

> "In addition, the alloy can be hot or cold mechanically worked to optimize grain size, strength, elastic modulus and toughness."

Clearly, such statement is completely devoid of any suggestion of a "**fine** grain size." Moreover, absolutely no suggestion is made as to what effect "optimization" of grain size could be expected to have, let alone what the optimization of grain size would entail (e.g. average size, size range, size distribution, minimum size, maximum size, etc?). Moreover, the fact that "grain size" is listed **along with** strength, elastic modulus and toughness as parameters that can be optimized does not suggest that the grain size would effect strength and toughness.

Notwithstanding the fact that "fine" grain size is not even generally mentioned, the Examiner goes on to assert that routine skill in the art would lead one to optimize the grain size to arrive at the claimed one to ten micron range. Yet the cited art fails to provide any motivation for doing so. Simply stating that grain size can be "optimized" in the absence of any reason for doing so is akin to stating that a material's surface texture or color or conductivity can be optimized. There is absolutely no teaching or suggestion that when confronted with the problem of the cracking and/or heavy slip band formation that had been encountered with regard to certain medical devices such as stents, one skilled in the art would be motivated

by the cited reference to undertake to "optimize" the grain size in an effort to solve such problem. Moreover, most any material has a multitude of physical characteristics that can be altered with no guarantee that it would have the intended effect. As such, the invention does not lie in the optimization of this parameter, but rather, the discovery that this particular parameter effects cracking and/or heavy slip band formation in medical device applications. Optimization of such parameter can only be undertaken AFTER such relationship has been recognized.

In view of the absence of any motivation provided by the Davidson reference and the unexpected reduction in cracking and/or heavy slip band formation when materials are used with a one to ten micron particle size, it is respectfully submitted that independent claims 1 and 41, as well as any claims depending therefrom, effectively avoid obviousness.

GROUND II

Claims 22 and 26-29, were rejected under 35 U.S.C. § 103(a) as obvious over Frantzen (USPN 5,843, 175) in view of Davidson (USPN 5,954,724).

While the Frantzen reference admittedly discusses the elements of a stent, the Davidson reference is again exclusively relied upon with regard to grain size. Accordingly, the same argument apply.

In rejecting independent claim 22, the Examiner again relies on the Davidson reference as teaching that grain size "can be optimized." The Examiner asserts that the Davidson reference at col. 8, lines 21-25 (Exhibit 2) teaches a medical device having a "fine grain structure." Such assertion is inaccurate. The passage relied on by the Examiner in fact merely states:

> "In addition, the alloy can be hot or cold mechanically worked to optimize grain size, strength, elastic modulus and toughness."

Clearly, such statement is completely devoid of any suggestion of a "**fine** grain size." Moreover, absolutely no suggestion is made as to what effect "optimization" of grain size could be expected to have, let alone what the optimization of grain size would entail (e.g. average size, size range, size distribution, minimum size, maximum size, etc?). Moreover, the fact that "grain size" is listed **along with** strength, elastic modulus and toughness as parameters that can be optimized does not suggest that the grain size would effect strength and toughness.

Notwithstanding the fact that "fine" grain size is not even generally mentioned, the Examiner goes on to assert that routine skill in the art would lead one to optimize the grain size to arrive at the claimed one to ten micron range. Yet the cited art fails to provide any motivation for doing so. Simply stating that grain size can be "optimized" in the absence of any reason for doing so is akin to stating that a material's surface texture or color or conductivity can be optimized. There is absolutely no teaching or suggestion that when confronted with the problem of the cracking and/or heavy slip band formation that had been encountered with regard to certain medical devices such as stents, one skilled in the art would be motivated by the cited reference to undertake to "optimize" the grain size in an effort to solve such problem. Moreover, most any material has a multitude of physical characteristics that can be altered with no guarantee that it would have the intended effect. As such, the invention does not lie in the optimization of this parameter, but rather, the discovery that this particular parameter effects cracking and/or heavy slip band formation in medical device applications. Optimization of such parameter can only be undertaken AFTER such relationship has been recognized.

In view of the absence of any motivation provided by the Davidson reference and the unexpected reduction in cracking and/or heavy slip band

formation when materials are used with a one to ten micron particle size, it is respectfully submitted that independent claim 22, as well as any claims depending therefrom, effectively avoid obviousness.

VIII. CLAIMS APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not obvious over any combination of the cited references and that the Examiner's rejections were therefore erroneous. Appellant respectfully requests reversal of the rejections of independent claims 1, 22 and 41 as well as all claims depending therefrom.

Respectfully submitted,

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LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Appealed Claims
2	U.S. Patent No. 5,954,724 Davidson